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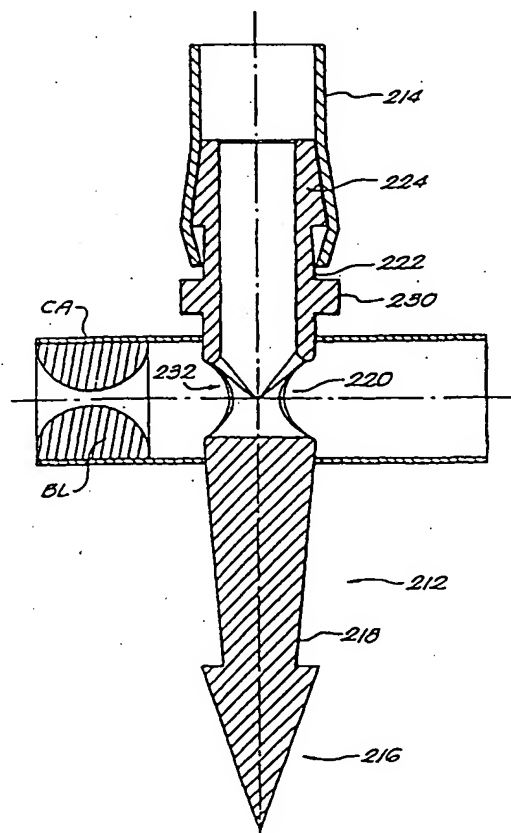
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: <b>PCT/US99/03484</b> (22) International Filing Date: <b>17 February 1999 (17.02.99)</b> (30) Priority Data: 60/099,720 10 September 1998 (10.09.98) US 60/099,691 10 September 1998 (10.09.98) US (71) Applicant (for all designated States except US): PERCARDIA, INC. [US/US]; Suite 434, 20 Trafalgar Square, Nashua, NH 03063 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): SANTAMORE, William, P. [US/US]; 1 Townsend Court, Medford, NJ 08055 (US). FURNISH, Greg, R. [US/US]; 2614 Top Hill Road, Louisville, KY 40206 (US). HALL, Todd, A. [US/US]; 1111 Crestview Way, Goshen, KY 40026 (US). BRIEFS, Nancy, M. [US/US]; 3 Horizon Circle, Nashua, NH 03060 (US). PHELPS, David, Y. [US/US]; 904 Shady Lane, Louisville, KY 40223 (US). WILK, Peter, J. [US/US]; 185 Westend Avenue, Apartment 22M, New York, NY 10023 (US). FURNISH, Simon, M. [US/US]; 2568 Woodbourne Avenue, Louisville, KY 40205 (US).		(74) Agent: RACITI, Eric, P.; Brown, Rudnick, Freed & Gesmer, P.C., One Financial Center, Boston, MA 02111 (US). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published***Without international search report and to be republished upon receipt of that report.*(54) Title: **BODY FLUID SHUNT DEVICE AND METHOD OF USE**

## (57) Abstract

An anastomosis shunt device (212) is provided to provide permanent or temporary bypass around a blocked vessel. In one embodiment, the device is a partially hollow stent (218) in the form of a spike (216) adapted to be positioned in the myocardium. An aperture (220) in the stent body (218) is in communication with a diversion tube (222) that ends in a connection portion (224) on the proximal end. The aperture (220) is positioned in the coronary artery, distal to the site of the blockage, and a venous or arterial graft attached to the connection portion (224). Another embodiment (10) is formed of a hollow lumen (12) with a distal end (14) having an opening (16) and a proximal end (20) having an aperture (18). In use, the distal end resides within the left ventricle and the aperture within the coronary artery, allowing blood to perfuse through the hollow lumen (12). In another embodiment, the device is formed as a rivet (512) for allowing blood flow between vessels. In any embodiment, one stent can be installed proximal of the blockage and one installed distally, and the two are connected to provide a bypass through which blood can flow around the blockage.



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WHAT IS CLAIMED IS:

1. An implantable body fluid shunt device for providing fluid communication between body vessels of a patient, said device comprising:
  - a generally elongated shunt body having proximal and distal ends, said shunt body being formed of a rigid, biocompatible material;
  - said shunt body having:
    - a first proximal aperture and at least one second aperture longitudinally spaced along said shunt body from said first aperture; and
    - a diversion tube having a predetermined shape providing fluid communication between said first aperture and said at least one second aperture;
  - wherein, in use, said device is implanted in a patient such that said first aperture is disposed within a first vessel, and said at least one second aperture is disposed in a second vessel.
2. The implantable shunt device of claim 1, wherein said shunt body further comprises a spike portion at a distal end thereof.
3. The implantable shunt device of claim 1, wherein said shunt body further comprises expansible retention members at a distal end thereof.
4. The implantable shunt device of claim 1, wherein said device provides transmyocardial blood perfusion, and wherein said second aperture is adjacent said distal end of said shunt body and in use is disposed within the left ventricle of a patient.
5. The implantable shunt device of claim 4, wherein the first aperture is adjacent said proximal end of said shunt body and in use is disposed within a coronary artery of a patient.
6. The implantable shunt device of claim 2, wherein the second aperture in use is situated within the coronary artery of a patient and wherein said spike portion is disposed within the myocardium.
7. The implantable shunt device of claim 6, wherein the first aperture is adjacent said proximal end of said shunt body, wherein said first aperture is disposed within a venous or

For illustrative purposes, it has been found that an anastomosis shunt device of the type depicted in FIG. 14 can be dimensioned to have a height of 12.5 mm, with a body width of about 2 mm, a flange diameter of about 2.8 mm, and an inside diameter of the diversion tube of about 1.4 mm. The spike can be dimensioned to be about 3 mm in height tapering to a width of about 2.1 mm. The aperture can be dimensioned to be about 1.4 mm in diameter, and can have an edge radius about the periphery of about 0.10 mm all around. An anastomosis shunt device of the type depicted in FIG. 18 can be dimensioned to have a height of 12.65 mm, with a body width of about 2.8 mm, a flange diameter of about 3.4 mm, and an inside diameter of the diversion tube of about 2.0 mm. The spike can be dimensioned to be about 3 mm in height tapering to a width of about 2.6 mm. The apertures can be dimensioned to be about 2.0 mm in diameter, and can have an edge radius about the periphery of about 0.10 mm all around.

Thus, the present bypass device and method provide significant improvements in present treatment of vascular blockages. It should be understood that while various anatomical features have been discussed herein for ease of reference, other uses of the instant anastomosis devices described herein are foreseen, and the disclosure should not be interpreted as limited strictly to use with the coronary artery, etc. It is intended that the present invention is applicable to a wide range of uses where vascular anastomosis is indicated. It is further intended that the present invention may be applicable during a wide variety of surgical techniques, from conventional sternotomy or "open chest" procedures, to minimally-invasive direct coronary artery bypass (MIDCAB) approaches.

Although the invention has been shown and described with respect to exemplary embodiments thereof, various other changes, additions and omissions in the form and detail thereof may be made therein without departing from the spirit and scope of the invention.

418'. Of course it should be understood that the apertures of this and the preceeding embodiment may be selectively placed and sized according to the desired application, the orientation of the blood vessels employed, and the location of anatomical features, blockages, etc.

FIG. 20 depicts a further alternative embodiment 412" that is similar to the embodiment depicted in FIGs. 18 and 19 except that there is no flange between the apertures 420 and 421, but rather a smooth transition area 430". The shunt body 418" is shown to have a gentle taper.

A further, "rivet" type embodiment 512 is depicted in FIG. 21. In this embodiment, instead of a spike, the hollow shunt body 518 is held into the wall of a vessel by one or more retention members 540, which are deployed after introduction. This embodiment will be further discussed with reference to FIG. 23.

FIG. 22 is a cutaway schematic representation of the shunt device 412' depicted in FIG. 19 mounted within the patient, with the spiked end resident within the myocardium MYO. The coronary artery CA and the bypass graft 414 are shown to be placed in fluid communication by the apertures 420', 421 in the shunt 412'. Of course, this illustration is illustrative of all side-by-side instant anastomosis devices described herein. Further, it should be noted that a hole may be located at position 436 to allow additional perfusion of the coronary artery CA, and that the aperture 420' could pass through both sides, as in devices 412 and 412". Further, it should be noted that the device could be mounted at an angle, as discussed hereinabove.

FIG. 23 is a cutaway schematic representation of the "rivet" type shunt device 512 depicted in FIG. 21 mounted within the patient, with the retention members 540 deployed. A flange 534 seals the incision and maintains a bearing surface against the bypass graft 514, which could be venous or arterial. An aperture 520 opens a channel into the hollow stent body 518, which terminates in an open end 542. In this illustrative arrangement, the open end 542 is resident within the coronary artery CA. The "rivet" type device advantageously provides a low profile, with the least amount of material in the vasculature and none in the myocardium. Of all the embodiments, the "rivet" offers the lowest flow restriction and the lowest possibility of turbulence.

bypass conduit. The detents can be in the form of hooks, clasps, split rings, pads, or the like in order to mechanically retain the bypass conduit onto the connector portion 324 of the diversion tube 322.

Referring now to FIG. 16, the shunt device 212 of FIG. 14 is depicted in cross-section, where like features are referred to by the same reference numerals. The view depicts the device 212 inserted into an artery, such as the coronary artery CA of a patient, and further depicts a blockage BL therein. A bypass conduit, for example a vein or artery graft, 214 is secured to the connector tube 224 of the diversion tube 222 above the flange 230. Optionally, an access port or hole may be placed along the shunt body opposite the aperture 220 at portion 232 to increase total flow and to maintain blood perfusion through the vessel bypassed. It also should be noted that although the Figure depicts the device 212 inserted perpendicular to the artery CA, the geometry of the device 212 allows it to be inserted at an angle without affecting its performance. This feature advantageously allows for more flexible application of the device during surgery, where perpendicular access to a vessel is not always available or convenient. FIG. 17 presents a view similar to that of FIG. 16, showing the barb 226 of the spike device implanted in the myocardium MYO of a patient for perfusing the coronary artery CA.

A side-by-side bypass device 412 is depicted in FIG. 18. In this device, the distal spike portion 416 is similar to that described above with respect to other embodiments, and has a barbed distal portion 426 having one or more barbs for anchoring the device. The proximal shunt portion 418 which resides in a vessel comprises an aperture 420 to allow blood to flow into the diversion tube 422. The aperture 420 passes through the shunt portion 418, and allows communication with the diversion tube to either side of the shunt portion 418. The proximal shunt portion 418 may be tapered. The top of the diversion tube 422 forms a connector portion with a second aperture 421 for communicating with a bypass conduit, such as an artery or vein graft. As above, a biocompatible fabric or mesh (not shown) can be incorporated into the structure of the device. A planar flange 430 serves to stabilize the artery and to self-seal the puncture therein. Similarly, a flange 434 is provided at the end of the diversion tube 422 to self-seal the puncture in the artery or vein graft.

FIG. 19 depicts an alternative embodiment 412' similar to the device of FIG. 18. The device of FIG. 19 has an aperture 420', which extends through only one side of the shunt portion

distal to the blockage. The device provides blood flow from the aorta to the coronary artery at a site distal to the blockage during the anastomosis.

Once blood flow has been established through the vein graft, the bypass device of the present invention may be removed.

FIG. 14 illustrates a further embodiment of the combination access/shunt device 212. The distal spike portion 216, as described above, provides access to the coronary artery by piercing completely therethrough and into the surrounding tissue. The barbed distal portion 226 having one or more barbs provides anchoring for the entire device. The proximal shunt portion 218 which resides in the vessel comprises an aperture 220 to allow blood to flow therein and from there, at a right angle, into the diversion tube 222 mounted proximally with respect to the aperture 220. The proximal shunt portion 218 may be tapered if desired to aid in the insertion of the device 212 through the coronary artery and into the heart wall. Mounted on top of the diversion tube 222 is a connector tube 224 for receiving a bypass conduit as described above. It will be noted that the connector tube 224 can be frusto-conical in order to provide a fluid-tight press-fit for the bypass. In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device. This fabric or mesh helps to seal the vessel to prevent bleeding and provides a structure that allows endothelial cells to infiltrate the device 212 and incorporate it into the surrounding tissues. A planar flange 230 serves to stabilize the artery and to self-seal the puncture therein.

FIG. 15 illustrates a further embodiment of the combination access/shunt device 312. The distal spike portion 316, as similar to that described above with respect to other embodiments, and has a barbed distal portion 326 having one or more barbs for anchoring the device. The proximal shunt portion 318 which resides in the vessel comprises an aperture 320 to allow blood to flow into the diversion tube 322. The proximal shunt portion 318 may be tapered. The top of the diversion tube 322 forms a tapered connector portion 324 for receiving a bypass conduit as described above. It will be noted that the connector portion 324 can be frusto-conical. In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device, as above. A planar flange 330 serves to stabilize the artery and to self-seal the puncture therein. Attached to the planar flange an distributed thereabout are at least one retaining members 323, which can comprise detents at the end thereof for engaging the

that allows endothelial cells to infiltrate the device 112 and incorporate it into the surrounding tissues.

Likewise, FIG. 9 illustrates an inverted U-shaped saddle portion 128 of the device 112, which serves a dual purpose. This saddle portion 128 fits over the artery when the combination access/shunt device 110 is installed therein, thereby stabilizing the artery. In addition, this saddle device 128 acts as a flange for self-sealing the puncture in the coronary artery CA formed by the barbed distal tip 126. Thus, blood flows through the diversion tube 122, and not outwardly through the puncture opening. If desired, a loop may be added the saddle portion 128 to allow the device to be sutured into the myocardium to prevent the device from migrating from its proper position.

FIG. 10 is an alternative embodiment of the spiked access/shunt device of FIG. 9 in which a planar flange 130 serves to stabilize the artery and to self-seal the puncture therein. FIGs. 11, 12 and 13 show additional views of three of the embodiments for device 112. FIG. 11 shows device 112 having a rounded configuration. FIG. 12 shows device 112 having a tapered configuration to aid in the insertion of the device 112. FIG. 13 shows device 112 having a collar or saddle 132 to help contain the artery may help with any possible migration problems.

In installing the device just described, the physician would make a small incision of a keyhole type in order to gain access to the blocked vessel. Vision could be obtained through thoroscopy or similar endoscopic procedure. Such access would be very minimally invasive. Once the area of blockage is located (through fluoroscopy, etc.), one or both of the combination access/shunt devices 112 are installed in the artery in the manner described above. The spiked devices would preferably be introduced by way of an automatic gun that would implant both spiked devices 112 and the conduit 114 at the same time in order to reduce procedure time and avoid bleeding. Alternatively, the spikes could be introduced individually, provided that bleeding is controlled.

The device can be sutured in place to provide for permanent bypass; alternatively, the device can be implanted temporarily to maintain the flow of blood through the coronary artery during bypass surgery. The device is implanted as described above. A vein graft is sutured in place, with one end anastomosed to the aorta and the other end to the coronary artery at a site



CA and shunts it into a diversion tube 122 mounted proximally with respect to the spiked portion 116 and the aperture 120. The diversion tube 122 is in fluid communication with the aperture 120 to allow blood flow from the coronary artery CA into the aperture 120 and into the diversion tube 122 as indicated by the arrows in FIG. 7. Mounted proximally with respect to the diversion tube 122 is a connector piece 124, which is also in fluid communication therewith. The combination access/shunt device 112 which is distal of the blockage BL may be constructed in a similar fashion or may have another configuration in which blood flows in the opposite direction as indicated by the arrows in FIG. 7. A bypass conduit 114 (FIG. 8), which is hollow, is mounted on the two connector portions 124 of the devices 112, as shown in FIG. 7, to allow blood to bypass the blockage BL. The conduit 114 may be constructed from a vein or artery graft taken from the patient or a donor, an artificial vein graft, or any other biocompatible tubing including one made from a metal or polymer. All these connections are fluid-tight, as described below in more detail, to avoid hemorrhaging. FIG. 7 illustrates the conduit portion 114 somewhat exploded away from the connector portions 124 in order to illustrate the manner in which the complete bypass system can be assembled.

FIG. 8 illustrates the conduit portion 114 of the bypass system 110 completely press-fit or snapped-down over the connector portions 124 (not shown), as will be the case in the final installation of the system.

FIG. 9 illustrates the combination access/shunt device 112 in greater detail. The distal spike portion 116, as described above, provides access to the coronary artery CA by piercing completely therethrough and into the surrounding tissue. The barbed distal portion 126 having one or more barbs provides anchoring for the entire device. The proximal shunt portion 118 which resides in the vessel comprises an aperture 120 to allow blood to flow therein and from there, at a right angle, into the diversion tube 122 mounted proximally with respect to the aperture 120, as indicated by the arrow in FIG. 9. The proximal shunt portion 118 may be tapered if desired to aid in the insertion of the device 112 through the coronary artery CA and into the heart wall. Mounted on top of the diversion tube 122 is a connector tube 124 for receiving the bypass conduit 114 as described above. It will be noted that the connector tube 124 is frusto-conical in order to provide a fluid-tight press-fit for the bypass. In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device. This fabric or mesh helps to seal the vessel to prevent bleeding and provides a structure

FIG. 6 also illustrates in schematic fashion the bypass device 110 of the present invention mounted both proximally and distally of the blockage BL by means of spiked combination access/shunt devices 112 and bypass conduit 114, described in more detail below. Initially, it should be noted that only the presently preferred embodiments of the present invention are described hereinbelow and only then in accordance with certain figures. Thus, it will be appreciated that the principles of the present invention apply to other similar devices and methods. For example, the present invention can be used to treat arteries and vessels other than the coronary artery. In addition, other types of blockages or vascular defects can be treated, including, for example, vascular bypass in other areas to alleviate problems such as aneurysms, deep vein thrombosis, or other types of calcified or stenosed vessels. The current system may be used to bypass obstructed bile ducts in the liver, or to direct the blood supply away from tumors in an effort to destroy them. Access devices using configurations other than spiked can also be implemented and bypass conduits can be integrated, attachable, or of other configurations. As used herein, the term "vessel" shall be deemed to embrace any body organ, vessel, space or vasculature, including artificial members or prior implants, which contains or can contain bodily fluid. Thus, the following description should not be construed to be limiting in any way.

Referring to FIG. 7 there is shown in greater detail one preferred embodiment of the bypass apparatus 110 of the present invention. The apparatus 110 is preferably formed of a biocompatible material, such as metal or a polymer. A pair of combination access/shunt devices 112 is shown proximally and distally of the blockage BL. The details of these spiked devices 112 are described below and shown in connection with FIGs. 9 and 10. In connection with the somewhat schematic representation of FIG. 7, it will be noted that each access/shunt device 112 pierces completely through the coronary artery CA on the outside, leaving the spiked portion 116 of the device 112 implanted in the wall of the heart wall HW. The spiked portion 116 provides not only piercing action through the coronary artery CA, but also into the tissue to provide anchoring and stabilization of the artery. The spiked portion 116 can be embedded in a tissue or passed completely through the tissue and into the left ventricle LV as shown in the distal device.

Each access/shunt device 112 (FIG. 9) is comprised of a shunt portion 118 having an aperture 120 which, in the case of the proximal device, receives blood from the coronary artery

The spike 30 is preferably anchored in place in the myocardium MYO as described above to prevent migration and to ensure that the free flow of blood from the left ventricle LV to the coronary artery CA is maintained.

Alternatively, as shown in FIGs. 5A and B, the spike 30 can be used to provide temporary blood flow during therapeutic procedures. For example, in typical coronary artery bypass surgery, a section of vein VG taken from the leg of the patient is attached at one end to the aorta AO and at the other end to a point distal to the blockage in the coronary artery CA. This surgery requires the delicate procedure of joining the vein graft VG to the aorta AO and to the coronary artery CA. This joining of the blood vessels is known as anastomosis. Normally, the patient is placed on a heart-lung machine to keep the blood oxygenated and flowing during this procedure, and the blood is diverted from the coronary artery CA to allow the physician to complete the anastomosis.

In one embodiment of the present invention, the spike 30 is used to maintain blood flow through the coronary artery CA during bypass surgery (FIG. 5A). The vein graft VG is loaded on top of the stent 30 prior to implantation. The spike 30 is implanted as described above, at the point of the vein graft VG anastomosis. The vein graft VG is sutured to the aorta and to the CA at a point distal to the blockage BL. If desired, the sutures can be preloaded onto the graft VG to facilitate the anastomosis. Once the vein graft VG has been attached, the spike 30 is removed, and blood flow occurs from the aorta AO, through the vein graft VG, and down the coronary artery CA. The spike 30 can be sutured in place during the anastomosis procedure for permanent attachment, if desired.

FIG. 6 illustrates in schematic fashion another embodiment of the bypass device 110 of the present invention. This embodiment is mounted both proximally and distally of the blockage BL by means of spiked combination access/shunt devices 112 and bypass conduit 114, described in more detail below. Referring to FIG. 6, there is shown a cross-sectional view of a typical heart anatomy including the aorta AO with a blockage BL or stenosis in the coronary artery CA, which is positioned along the external surface of the heart wall HW. As is well known, the coronary artery supplies blood pumped from the left ventricle LV to the aorta AO and into the heart muscles or myocardium MYO.

that is larger than the diameter of the lumen (FIG. 2), to help anchor the spike 10 in place and prevent it from migrating or passing completely through the coronary artery CA. This head portion 22 also acts to seal the puncture in the coronary artery CA formed by the distal tip of the spike 14. The blood therefore flows through the spike 10 and downstream within the coronary artery CA, and not outwardly through the puncture opening. If desired, this portion of the device 22 may be sutured into the surrounding tissue to prevent the device 10 from migrating from its proper position. Additional anchoring in the form of sutures or other means 24 is also preferably provided along the central portion of the spike 12. Anchoring the device 12 into the myocardium MYO prevents migration of the spike 10 from its proper position.

As illustrated in FIG. 2, the spike 12 may also include a second opening 25 at its proximal end 20 opposite from the first opening 18. This second opening 25 allows for the perfusion of blood from the coronary artery CA as shown by the arrow in Figure 2.

In installing the device just described, the physician would make a small incision of a keyhole type in order to gain access to the blocked vessel. Vision could be obtained through thoroscopy or similar endoscopic procedure. Such access would be very minimally invasive. Once the area of blockage is located, the spike is implanted the body in the manner described above. The spiked device would preferably be introduced by way of an automatic gun or needle in order to reduce procedure times and avoid bleeding. Of course, the spike could be implanted in other ways as well.

One method for implanting the device is illustrated in FIGs. 3A-C. The spike 30 is first mounted over a needle 32 (FIG. 3A), and the needle 32 is used to puncture the coronary artery CA, myocardium MYO and left ventricle LV (FIG. 3B). The needle 32 is then removed (FIG. 3C) and the anterior hole in the coronary artery CA is closed using sutures 34 or other suitable methods.

In an alternate method illustrated in FIGs. 4A and B, a flap FL is first cut in the wall of the coronary artery CA and the needle 32 bearing the spike 30 is inserted through the flap FL and through the other side of the coronary artery CA, through the myocardium MYO, and into the left ventricle LV. The needle 32 is withdrawn, leaving the spike 30 in place. The flap FL is then closed using sutures 34 or other suitable means.

FIG. 1 also illustrates in schematic fashion one embodiment of the bypass device 10 of the present invention implanted distal to the blockage BL in the coronary artery CA. It should be noted that only the presently preferred embodiments of the present invention are described hereinbelow and only then in accordance with certain figures. Thus, it will be appreciated that the principles of the present invention apply to other similar devices and methods. For example, the present invention can be used to treat arteries and vessels other than the coronary artery. In addition, other types of blockages or vascular defects can be treated, including, for example, vascular bypass in other areas to alleviate problems such as aneurysms, deep vein thrombosis, or other types of calcified or stenosed vessels. The current device may be used to bypass obstructed bile ducts in the liver, or to direct the blood supply away from tumors in an effort to destroy them. Access devices using configurations other than spiked may also be implemented. Thus, the following description should not be construed to be limiting in any way.

Referring to FIG. 2 there is shown in greater detail one preferred embodiment of the bypass apparatus 10 of the present invention. The apparatus 10 is preferably formed of a biocompatible material, such as metal or a polymer. The apparatus 10 is shown piercing the coronary artery CA distal to the site of the blockage BL. The details of this spiked device 10 are described below. In connection with the somewhat schematic representation of FIG. 2, it will be noted that the device 10 pierces completely through the coronary artery CA, with the central portion of the device 12 positioned within the myocardium MYO and the distal portion of the device 14 implanted in the left ventricle of the heart LV.

Each shunt device 10 (FIG. 2) is comprised of a central portion formed by a hollow lumen 12 having an aperture or opening on each end 16, 18. One opening 16 receives blood from the left ventricle LV and shunts it through the hollow lumen 12 and out the other opening 18 which is positioned in the coronary artery CA. The spike 10 therefore allows oxygenated blood to flow directly from the left ventricle LV and into the coronary artery CA, as indicated by the arrows in FIG. 2.

The distal end of the spike 14 may be blunt (FIG. 4B) or tapered if desired (FIG. 2) to aid in the insertion of the device 10 through the coronary artery CA, the heart wall MYO and the left ventricle LV. The proximal end of the spike 20 is preferably provided with a head portion 22

FIG. 21 is a perspective view of a shunt device according to a thirteenth embodiment of the present invention;

FIG. 22 is a close-up cross-sectional view of a coronary artery and the myocardium of a patient and the shunt device according to FIG. 19;

FIG. 23 is a close-up cross-sectional view of a coronary artery of a patient and the shunt device according to FIG. 21.

#### Detailed Description of Illustrative Embodiments

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood flows from the heart to the aorta, into the coronary artery, and on to the rest of the body. In some individuals, plaque builds up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. In order to restore the flow of oxygenated blood through the coronary artery, or to provide for the temporary flow of blood around the blockage, the present invention provides for the shunting of blood to a site in the coronary artery, which is distal to the blockage.

In one embodiment of the present invention, a single hollow spike is inserted through the walls of the coronary artery and the myocardium and into the left ventricle of the heart, which lies beneath the coronary artery. The hollow spike is positioned such that the openings on either end of the spike are within the coronary artery and the left ventricle. Blood flows through the opening in the left ventricle, through the hollow spike and out of the opening positioned in the coronary artery distal to the site of the blockage.

Referring to FIG. 1, there is shown a cross-sectional view of a typical heart, aorta AO, and the coronary artery CA having a blockage BL therein. The coronary artery CA lies along the external surface of the wall of the heart MYO. As is well known, the coronary artery CA supplies oxygenated blood pumped from the left ventricle of the heart LV and through the aorta AO to the heart muscle or myocardium MYO.

FIG. 10 is a perspective view of a fourth embodiment of the present invention, formed of a shunt device having a spike on its distal end;

FIG. 11 is a perspective view of a shunt device according to a fifth embodiment of the present invention;

FIG. 12 is a perspective view of a shunt device according to a sixth embodiment of the present invention;

FIG. 13 is a perspective view of a shunt device according to a seventh embodiment of the present invention;

FIG. 14 is a perspective view of a shunt device according to a eighth embodiment of the present invention;

FIG. 15 is a perspective view of a shunt device according to a ninth embodiment of the present invention;

FIG. 16 is a close-up cross-sectional view of a coronary artery blockage and the shunt device according to FIG. 14;

FIG. 17 is a close-up cross-sectional view of a coronary artery blockage and the myocardium of a patient and the shunt device according to FIG. 14;

FIG. 18 is a perspective view of a shunt device according to a tenth embodiment of the present invention;

FIG. 19 is a perspective view of a shunt device according to a eleventh embodiment of the present invention;

FIG. 20 is a perspective view of a shunt device according to a twelfth embodiment of the present invention;

invasive manner using thoroscopy or other endoscopic procedure. Of course, open surgery or other vascular access is also possible.

#### Brief Description of the Drawings

The foregoing and other features and advantages of the present invention will be more fully understood from the following detailed description of an illustrative embodiment, taken in conjunction with the accompanying drawing in which:

FIG. 1 is a small-scale cross-sectional view of a heart with a blockage in the coronary artery, illustrating one embodiment of the bypass device of the present invention;

FIG. 2 is a close-up perspective view of a first embodiment of the device of FIG. 1 invention shown implanted in the myocardium, with the coronary artery, myocardium and left ventricle of the heart shown cut-away;

FIGs. 3A-C illustrate a method for implanting the device of FIG. 1;

FIGs. 4A-B illustrate an alternate method for implanting the device of FIG. 1;

FIGs. 5A-B illustrate the temporary use of the stent during a coronary bypass procedure;

FIG. 6 is a small scale cross-sectional view of a heart with a blockage in the coronary artery, and further illustrating a second embodiment of the bypass device of the present invention;

FIG. 7 is a close-up cross-sectional view of the blockage in the coronary artery and illustrating in greater detail a second embodiment of the spiked bypass device of FIG. 6;

FIG. 8 is a perspective view of the spiked bypass device and conduit according to a second embodiment of the present invention;

FIG. 9 is a close-up view of a third embodiment of the present invention formed of a single shunt device having a spiked distal tip;



to deliver a vein graft, and to provide for the passage of blood around the blockage until the anastomosis of the graft is complete.

In another embodiment, a first combination access and shunt device is used to direct the blood from the coronary artery proximal to the stenosis. A second access and shunt device is located in the vessel distal of the stenosis to receive the diverted blood and allow it to continue on its course downstream. The combination access/shunt device comprises a spike element for providing access to the vessel and anchoring the system in place. The spike pierces the artery from the outside and travels completely through it and into the myocardium or other heart tissue adjacent the coronary artery. The spike has a spike or barb or series of barbs on its distal end and is otherwise designed so that it has substantial resistance to pull back or exit from the vessel. As noted, the spike pierces through the vessel from an outside space or tissue in a transverse manner. Mounted on top of the spike is a shunt device that comprises an aperture and a diversion conduit. With the spike in its anchoring position, the shunt device is located partially in the vessel and partially outside of the vessel from the direction in which the spike entered. The aperture resides in the vessel to allow blood to enter therein and subsequently travel to the diversion tube, which is in fluid communication with the aperture. This provides the shunting of blood into the diversion tube of the combination access/shunt device.

Mounted on top of the diversion tube is a connector piece which mates with a bypass conduit. These elements are also in fluid communication to allow the blood to bypass the blockage and to be shunted to a location distal thereof. At such distal location, another similar combination access/shunt device can be placed to allow the shunted blood to re-enter the artery in a free-graft configuration, and continue on its path downstream. Of course, a single device can be used distal of the restriction and connected to an appropriate graft for revascularization.

The apparatus of the present invention is preferably implanted in a minimally invasive manner using thoroscopy or another endoscopic procedure. Of course, open surgery or other means of vascular access are also possible. The apparatus can be implanted permanently, or can be used temporarily to provide a bypass system during various surgical procedures, including coronary bypass procedures.

The apparatus of the present invention can advantageously be implanted in a minimally

formed, for example, by a drill, needle, Seldinger wire, dilating wires or catheters, or other devices prior to stent placement and expansion.

Thus, there is a continuing need for improved bypass methods that allow for the realization of increased long-term patency rates, and that are less physically traumatic to the patient.

#### Summary of the Invention

The present invention is directed to a system and method for providing a perfusion, reperfusion or bypass system that can be delivered in a minimally invasive procedure which avoids the sternotomy and other intrusive procedures normally associated with coronary bypass surgery. It also frees the physician from the multiple anastomoses necessary in the current process. At the same time, the system can be implemented in a minimally invasive manner. Alternatively, it may also provide for temporary blood flow through the coronary artery during the anastomosis procedure.

The present system is used to direct the flow of blood around the blocked portion of the vessel. In one embodiment, a shunt is used to direct blood directly from the left ventricle of the heart to the coronary artery at a point distal to the blockage. According to one aspect of the invention, the shunt comprises a rigid, generally elongated stent in the form of a single spike having an opening at either end, and adapted to be positioned in the myocardium. The coronary artery, the myocardium and the wall of the left ventricle of the heart are pierced by the spike from an outside space or tissue in a transverse manner to provide a channel completely through from the coronary artery to the left ventricle of the heart. An opening located on the distal end of the spike is positioned within the left ventricle. An opening on the proximal end of the spike is positioned in the coronary artery. Oxygenated blood is pumped from the left ventricle, through the distal opening, through the hollow central portion of the spike, out of the proximal opening and into the coronary artery distal to the blockage. The spike is anchored in the myocardium to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage.

Alternatively, the spike can be used temporarily to maintain blood flow through the coronary artery during therapeutic procedures, such as coronary bypass. The spike can be used

artery (ITA) compared with the SV. The SV, in fact, has only been shown to have a 10-year patency rate of 50%. Since the mid 1980's, not only the ITA, but also the alternative arterial conduits have been increasingly used. These conduits include the gastroepiploic artery (GEA), inferior epigastric artery (IEA), and radial artery (RA), which have been used primarily as supplements to both the right and left ITA.

Although the use of arterial conduits results in demonstrably better long-term patency, use of arteries in place of the SV often requires complex technical challenges, such as free grafts, sequential anastomosis, and conduit-to-conduit anastomosis. Some of the reasons for the difficulty in using arterial conduits reside in the fact that they are much more fragile than the SV and therefore easier to damage, and due to their smaller size, easier to occlude completely or partially through technical error during grafting.

Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence periods are prolonged.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage, or due to the risk of emboli formation.

One bypass technique employed in the prior art is taught by Wilk (U.S. 5,409,019 and 5,429,144). These Wilk references teach a minimally-invasive method of transluminal catheter delivery of a collapsed stent, which is subsequently introduced through the myocardial wall from an adjacent coronary artery and expanded to provide a bypass shunt between the left ventricle and the adjacent coronary artery. This prior art technique teaches the delivery of a transmyocardial bypass shunt in a collapsed, reduced-profile configuration, which requires radial expansion subsequent to delivery in a bore pre-formed in the myocardial wall. The bore is

## BODY FLUID SHUNT DEVICE AND METHOD OF USE

### Priority

This application is a continuation-in-part of US Provisional Application 60/099,720 filed on September 10, 1998.

### Field of the Invention

The present invention relates generally to fluid shunting and perfusion, and more particularly to an apparatus and method for bypassing a restricted blood vessel segment using a relatively elongated, rigid shunt implant.

### Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. In fact, about 1.1 million "open heart" procedures are performed each year, and current estimates are that approximately 4.8 million people suffer from some degree of congestive heart failure.

When coronary arteries or other blood vessels become clogged with plaque, the results are at the very least impairment of the efficiency of the heart's pumping action. On the more severe side of the scale are heart attack and death. In some cases, clogged arteries can be unblocked through minimally invasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

In a bypass operation, one or more arterial or venous segments are harvested from the body and then surgically inserted between the aorta and the coronary artery. The inserted vessel segments, or transplants, act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the US every year.

Coronary artery bypass grafting (CABG) has been used for more than 30 years. Initially, the saphenous vein (SV) served as the principal conduit for coronary bypass, but studies over the last dozen years have shown a 35-40% increase in 10-year patency rate for the internal thoracic

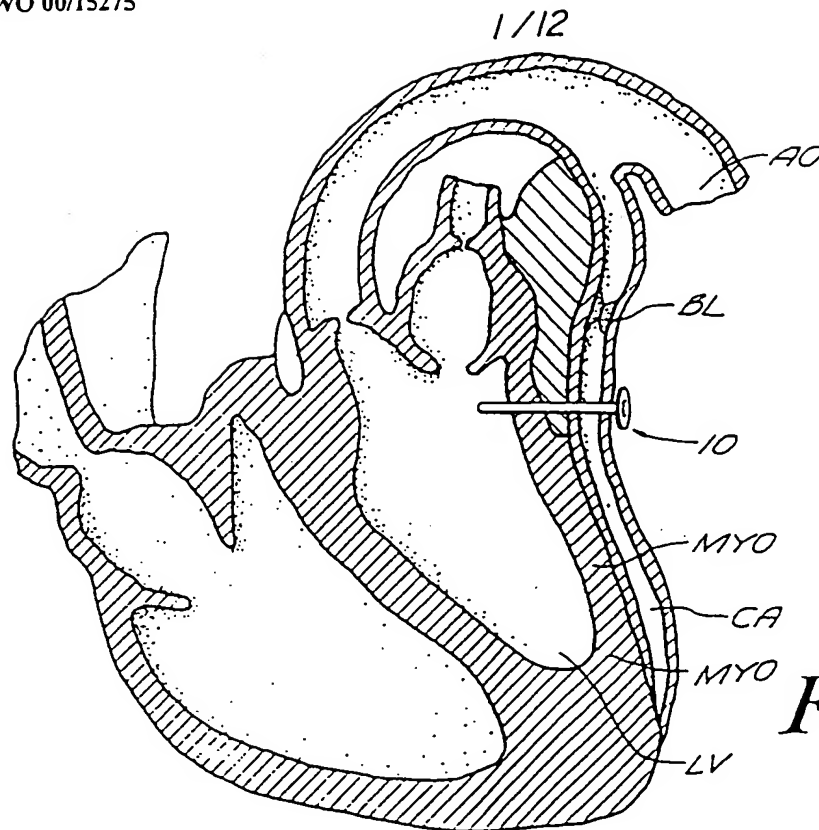
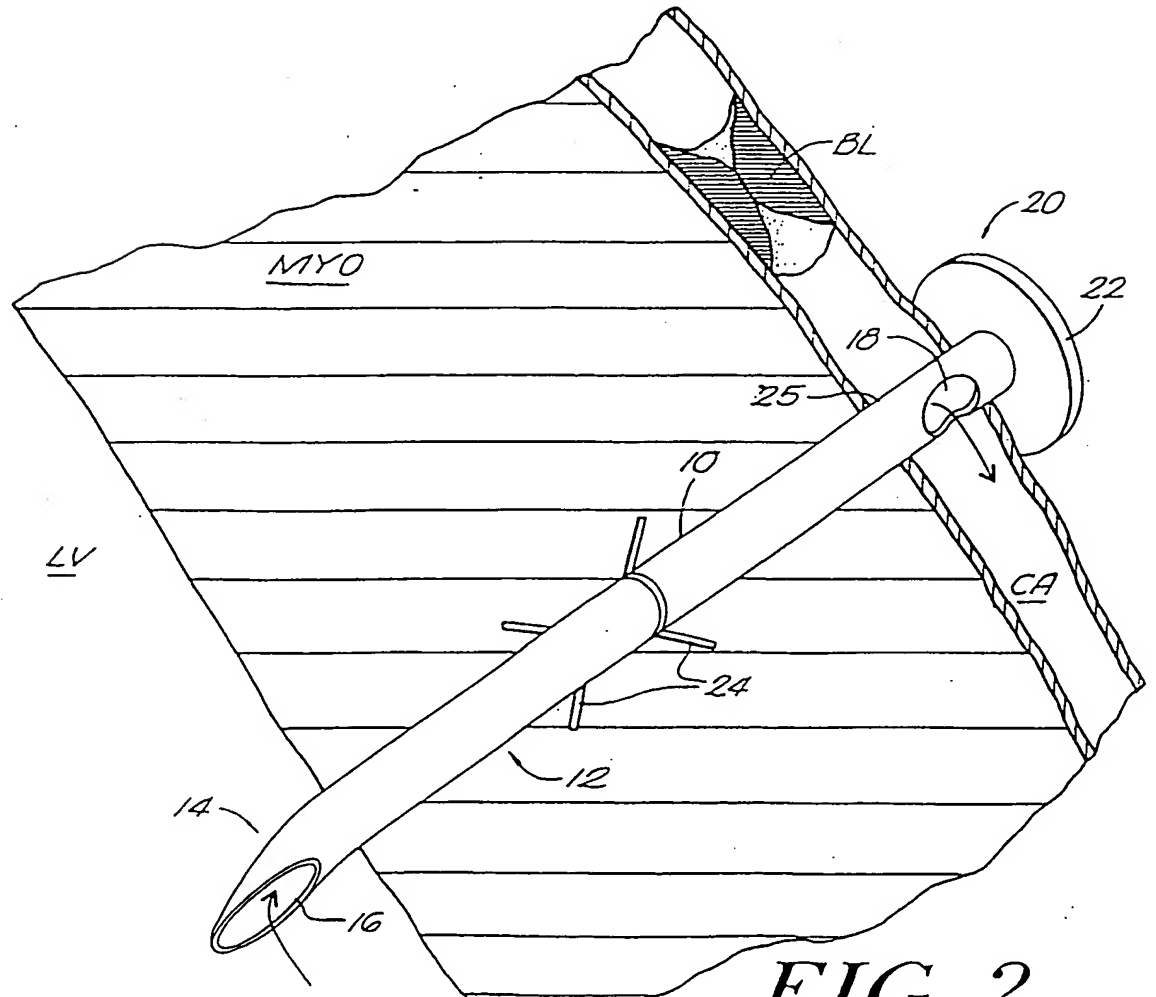


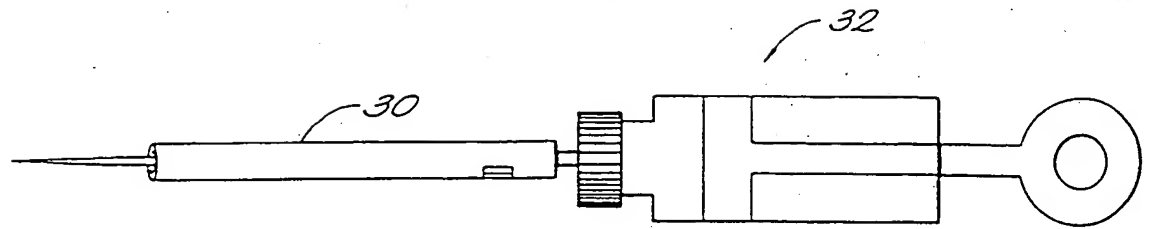
FIG. 1



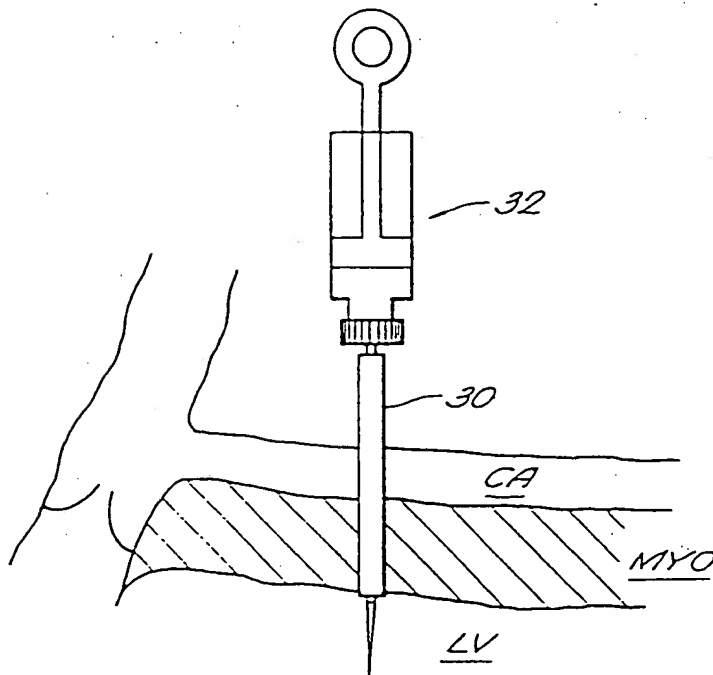
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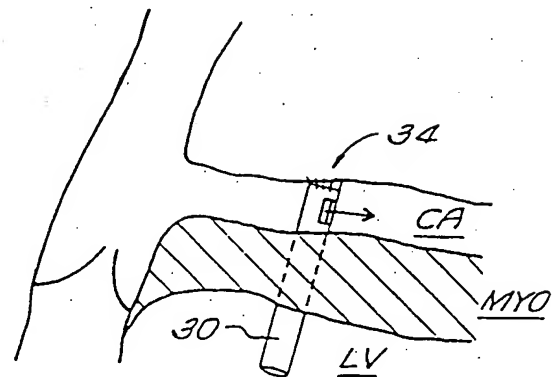
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*FIG. 3A*



*FIG. 3B*

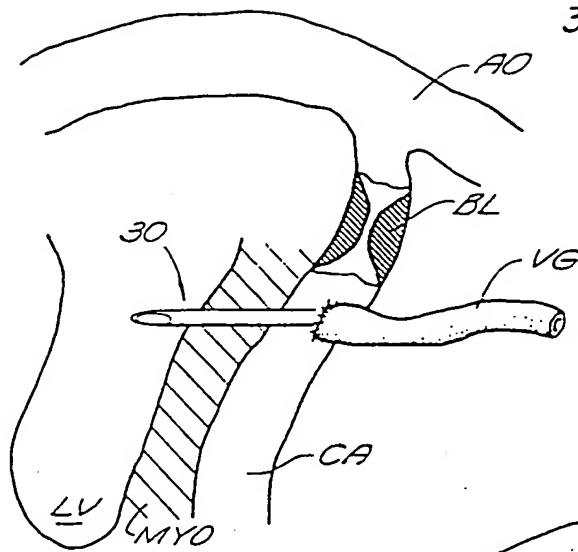


*FIG. 3C*

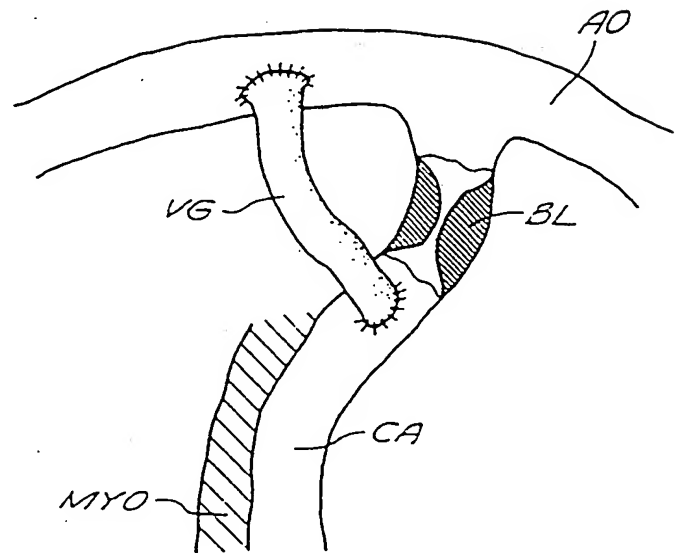
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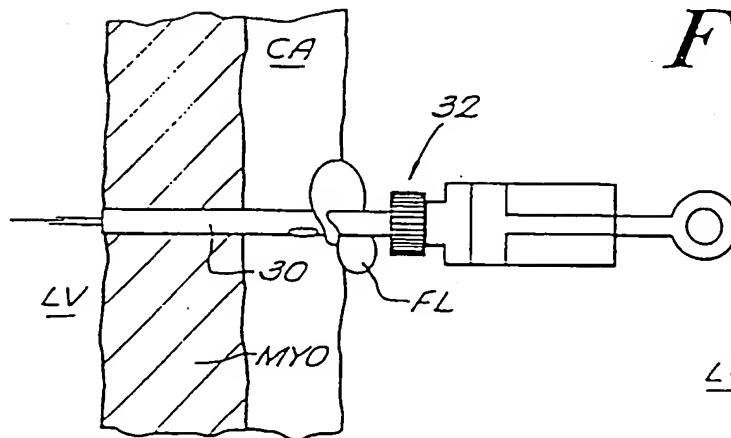
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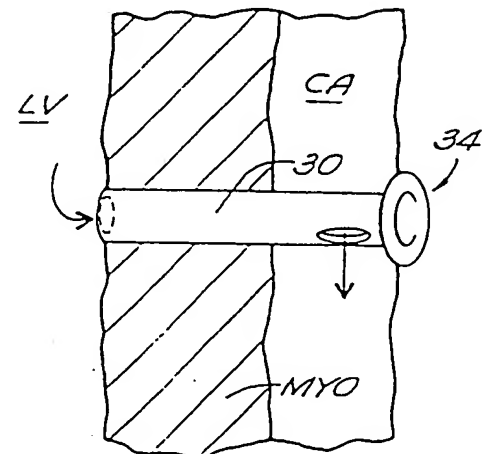
**FIG. 5A**



**FIG. 5B**



**FIG. 4A**

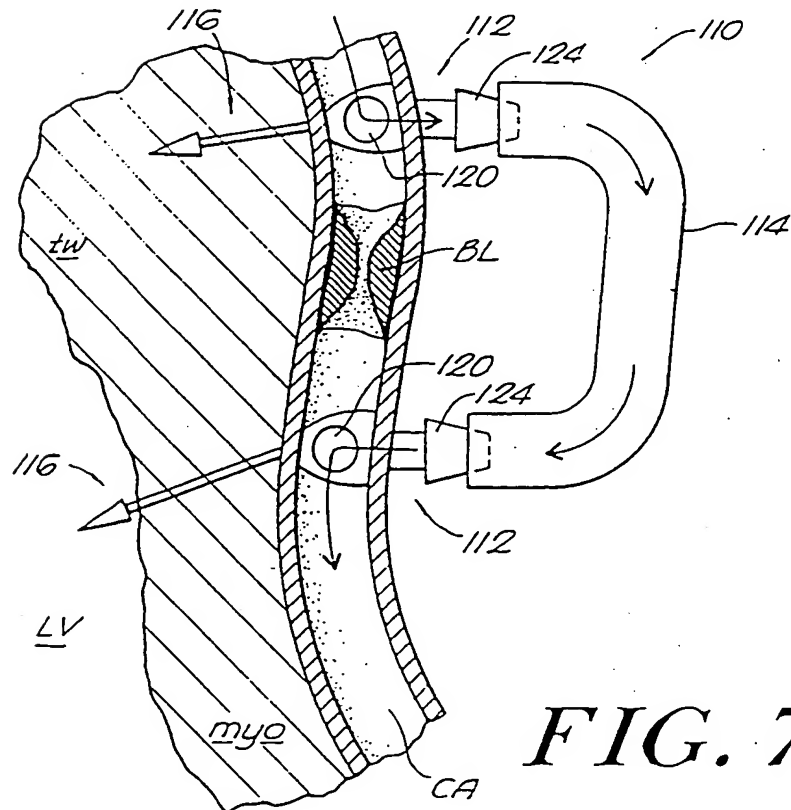
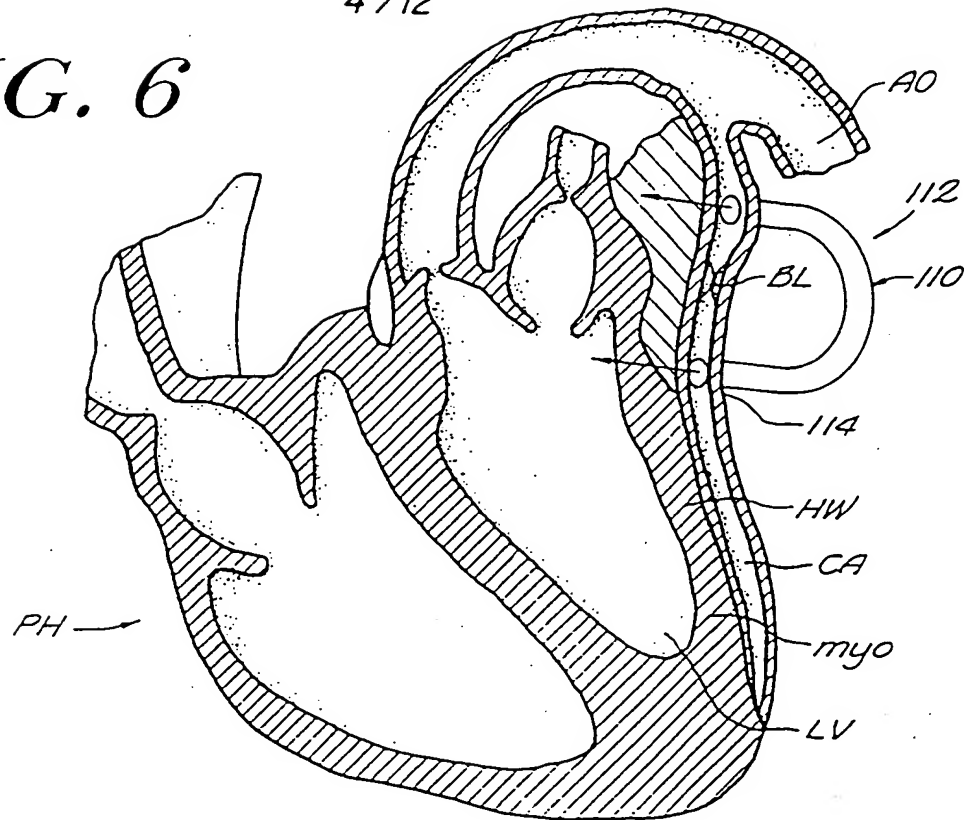


**FIG. 4B**

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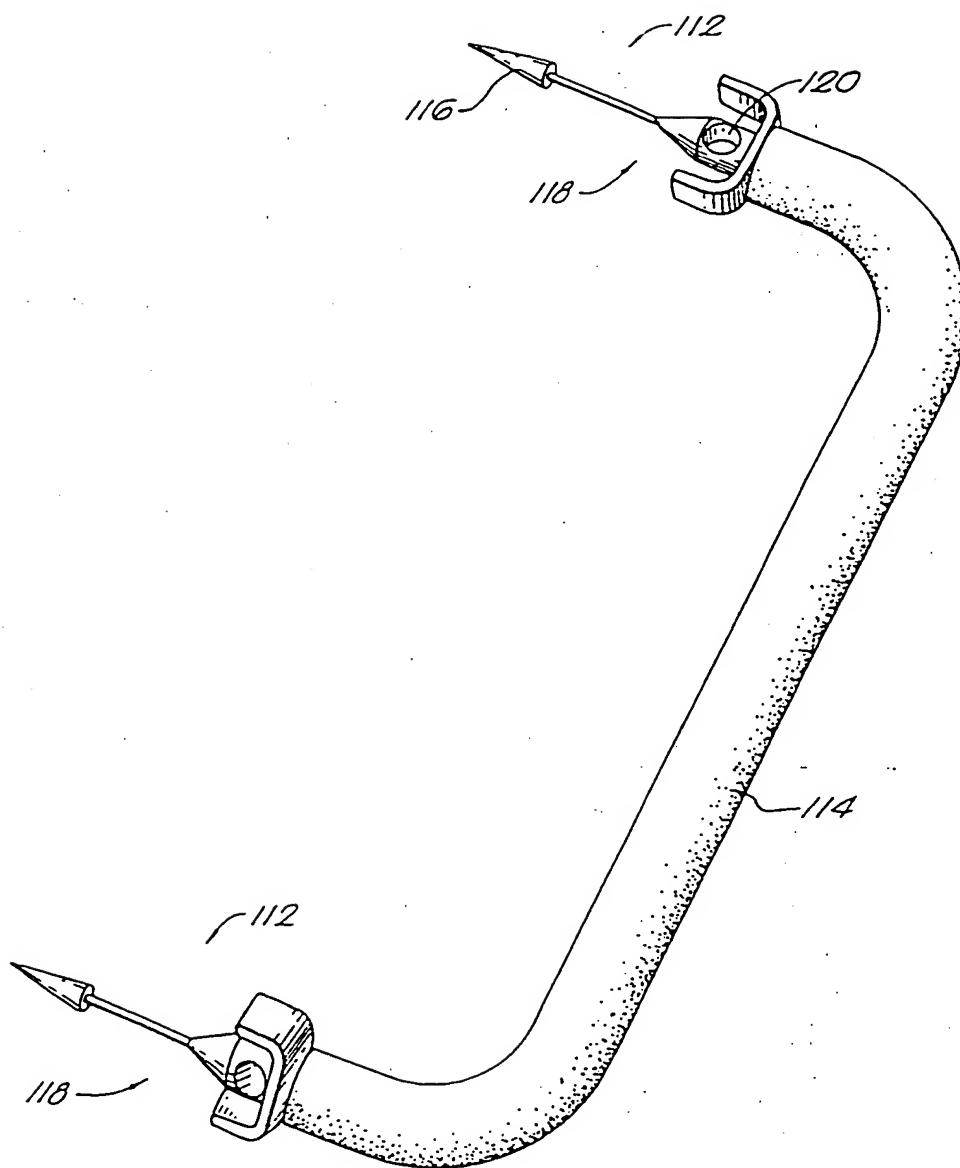
**FIG. 6**



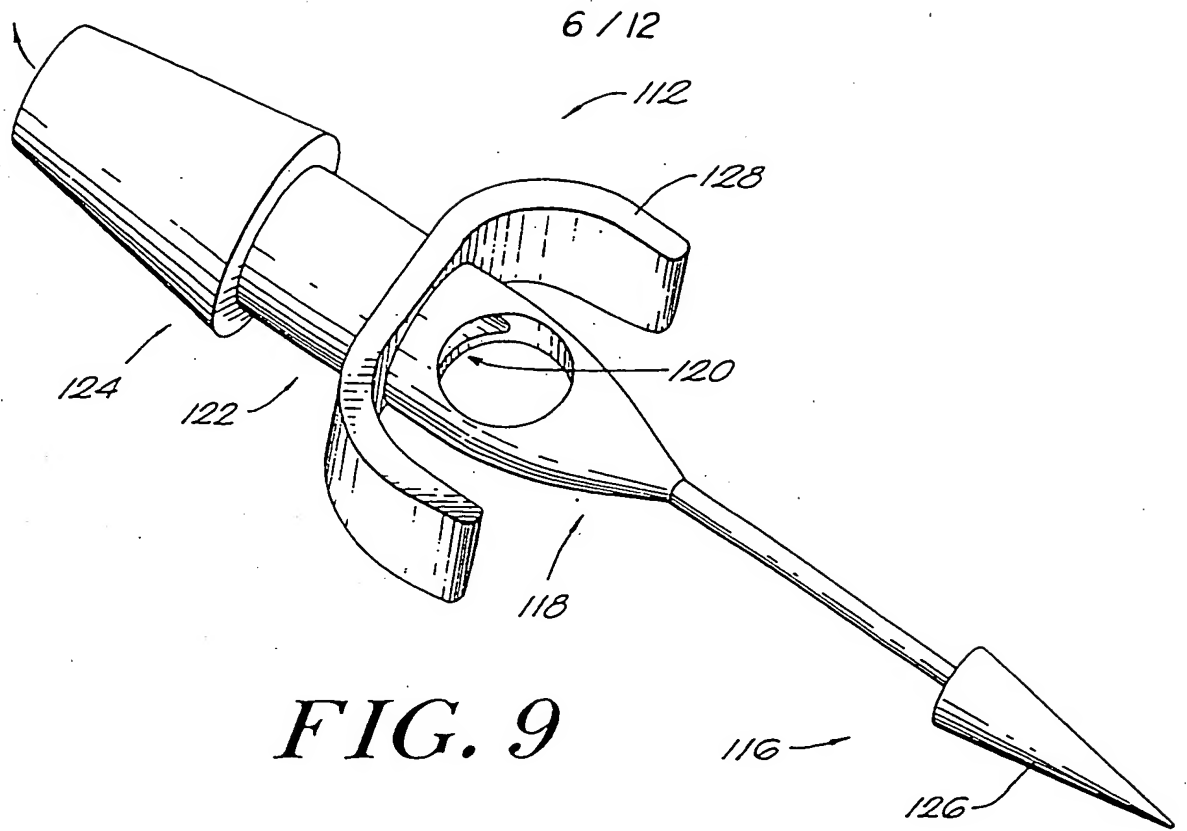
**FIG. 7**

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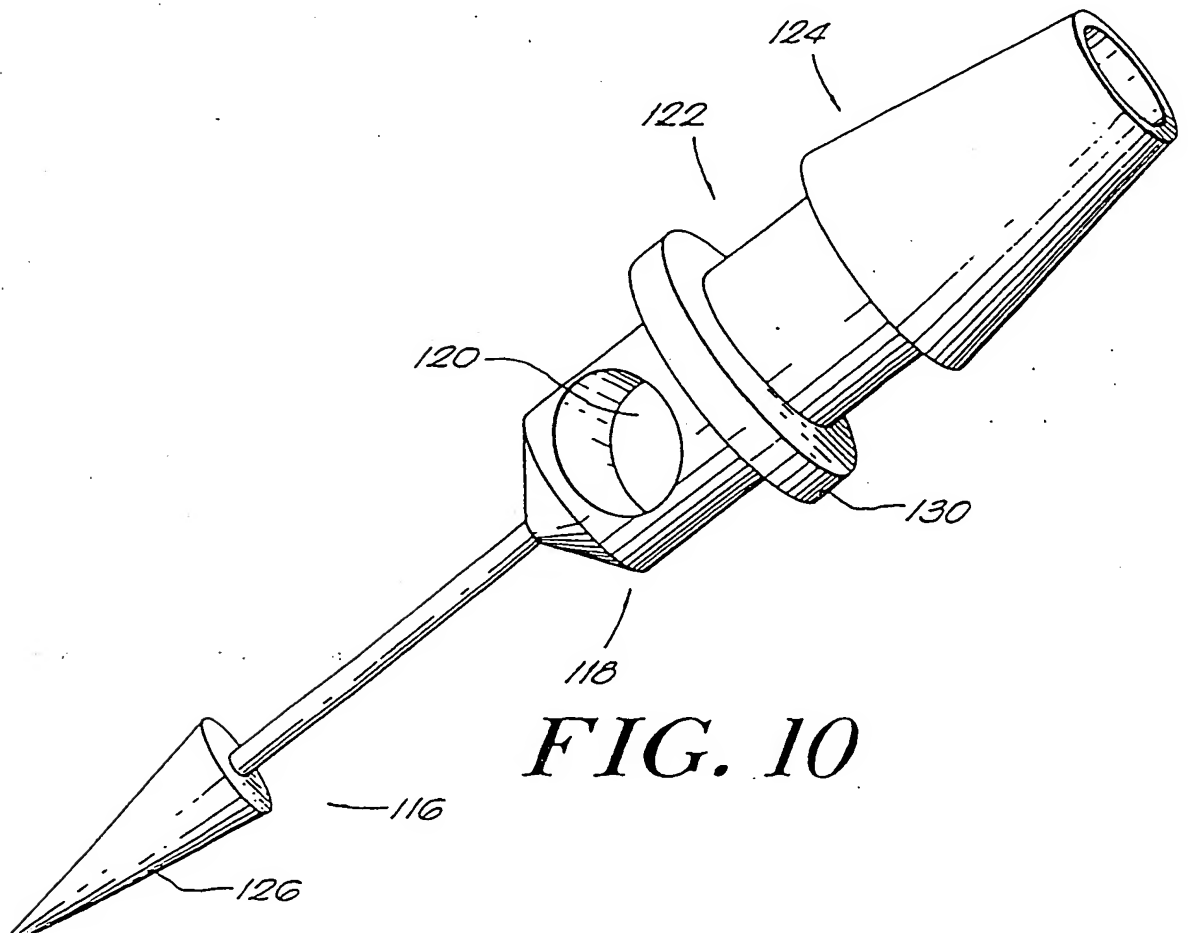
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*FIG. 8*

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**FIG. 9**

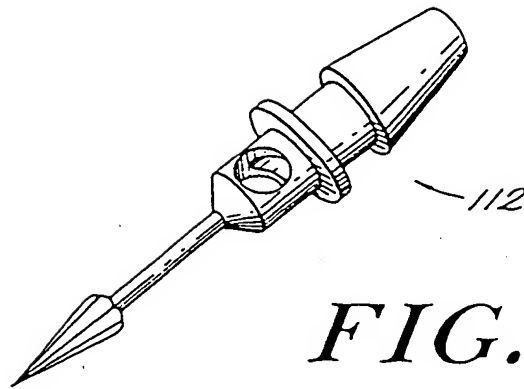


**FIG. 10**

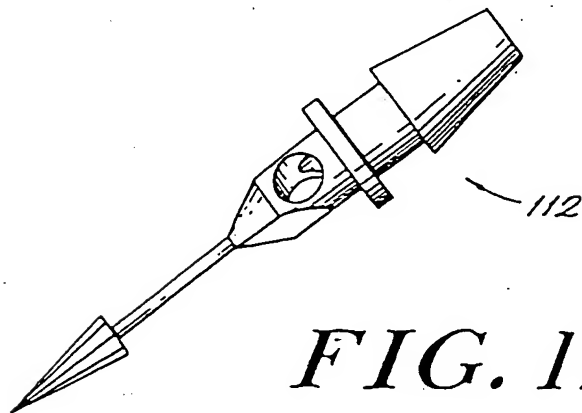
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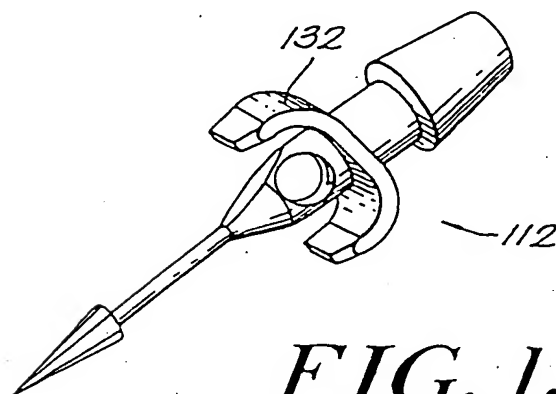
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*FIG. 11*



*FIG. 12*



*FIG. 13*

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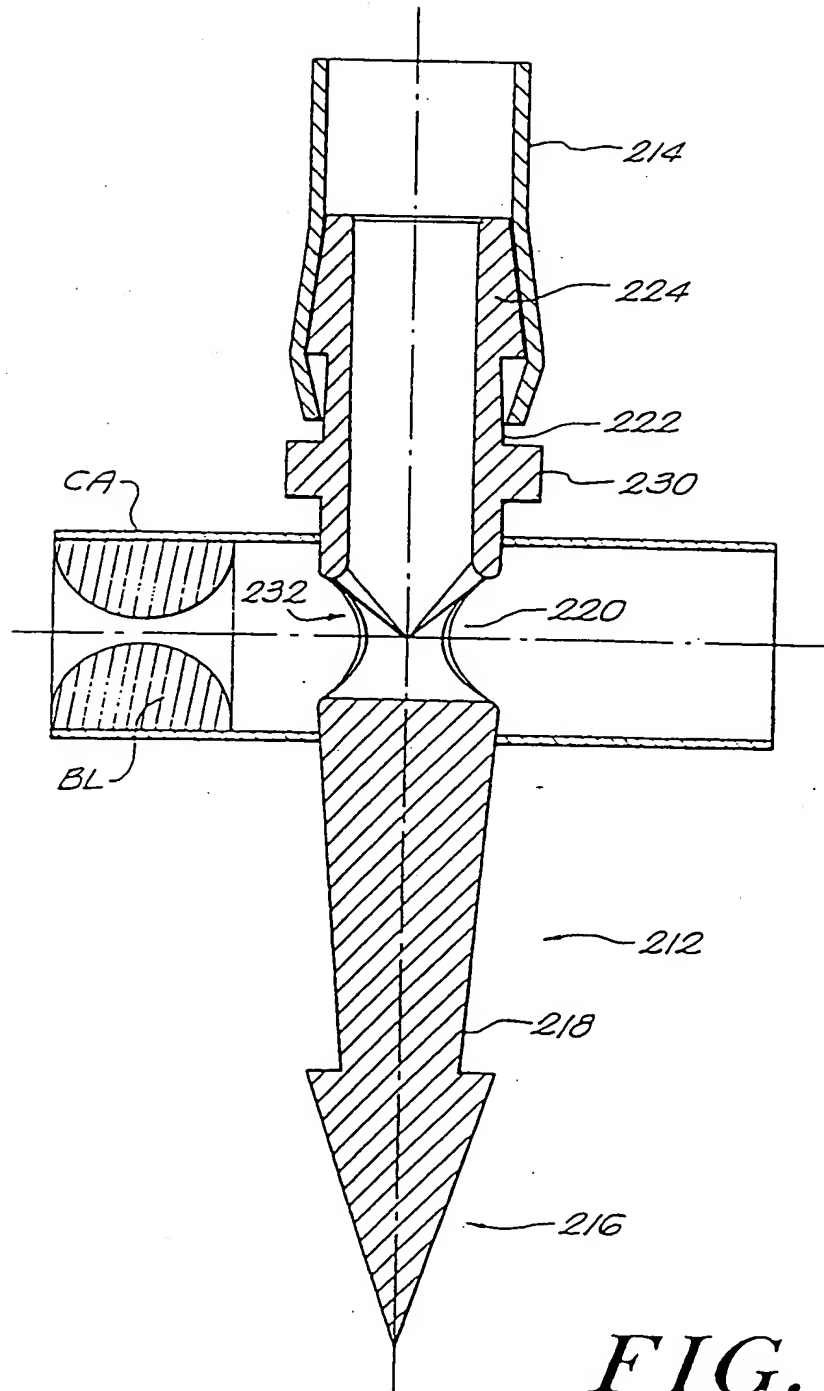


FIG. 16

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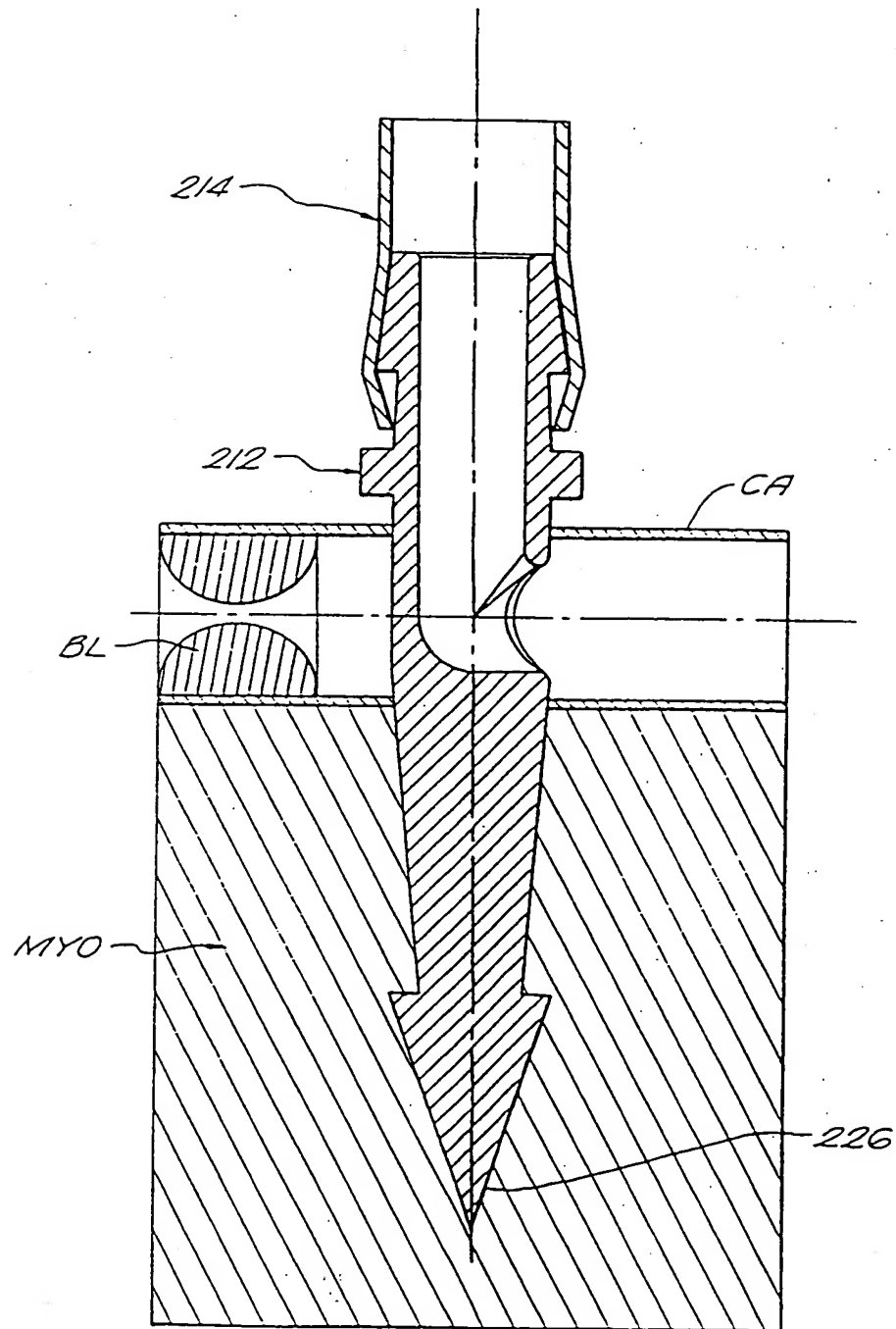
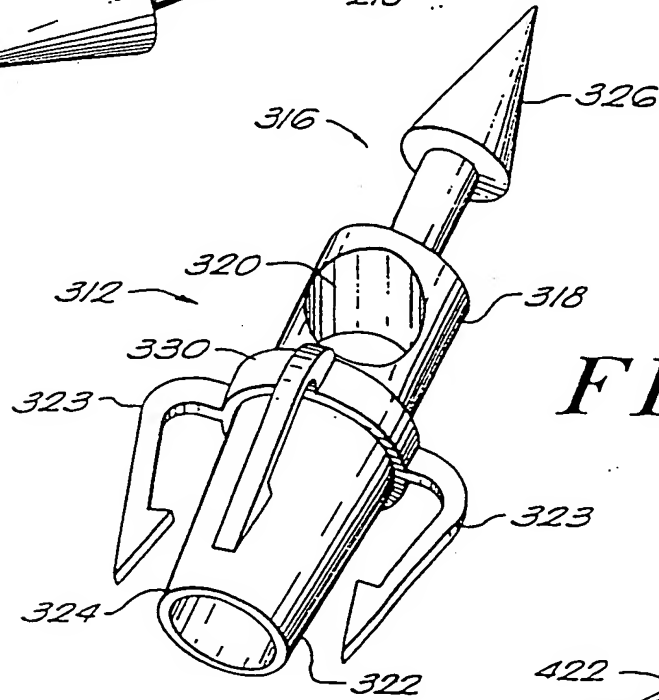
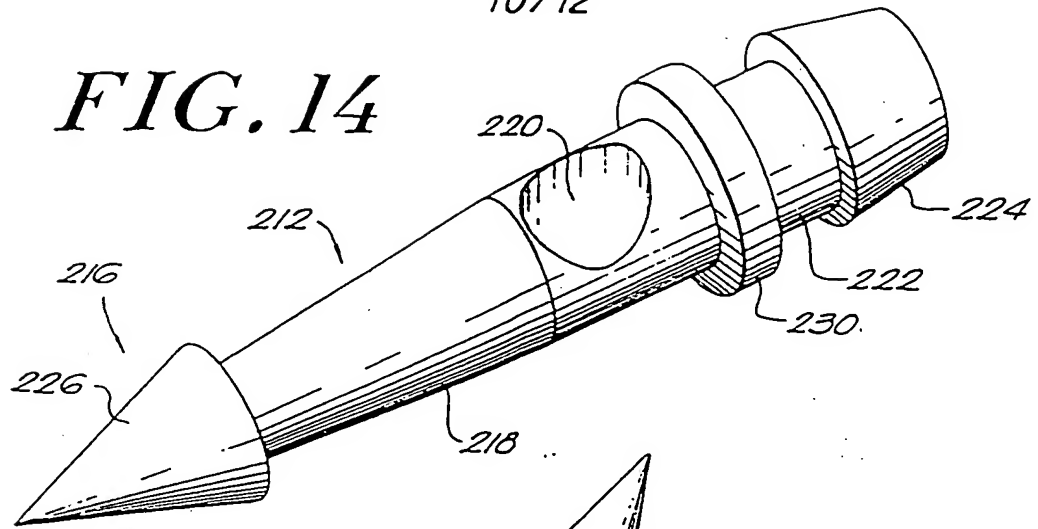


FIG. 17

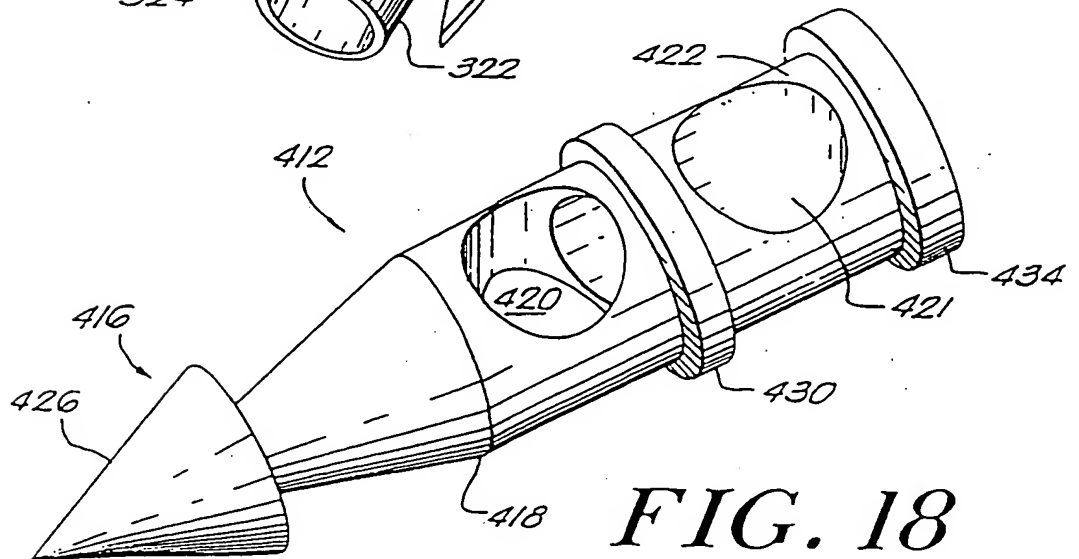
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**FIG. 14**



**FIG. 15**

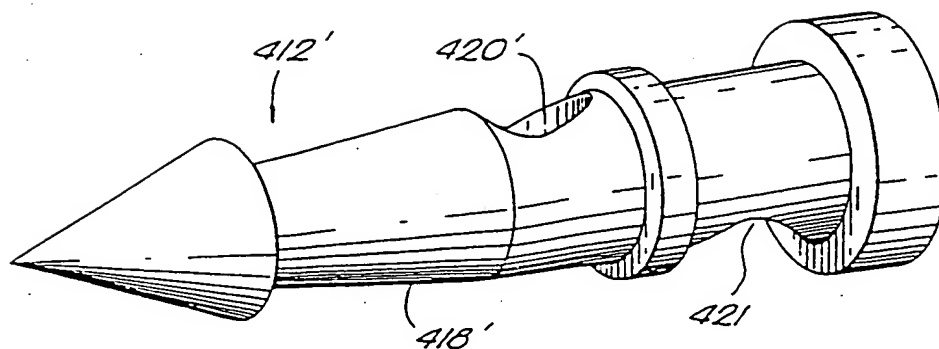


**FIG. 18**

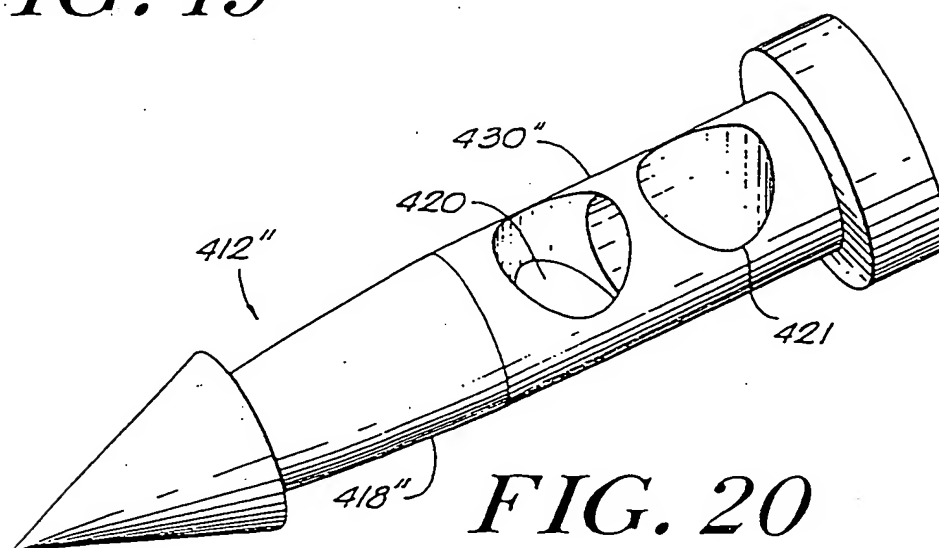
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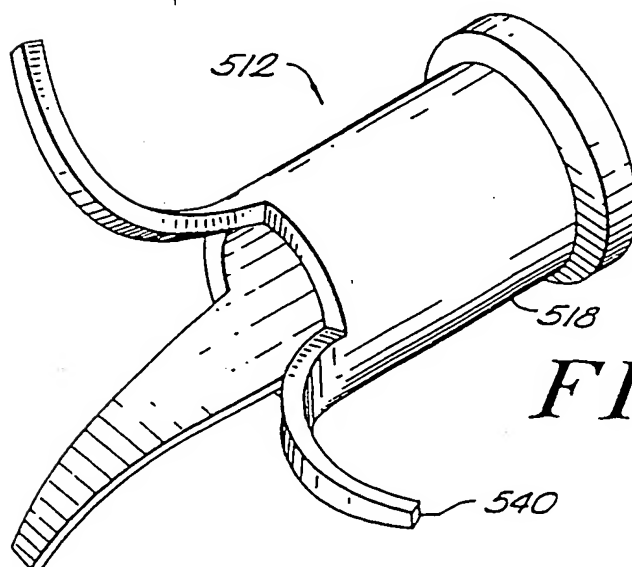
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**FIG. 19**

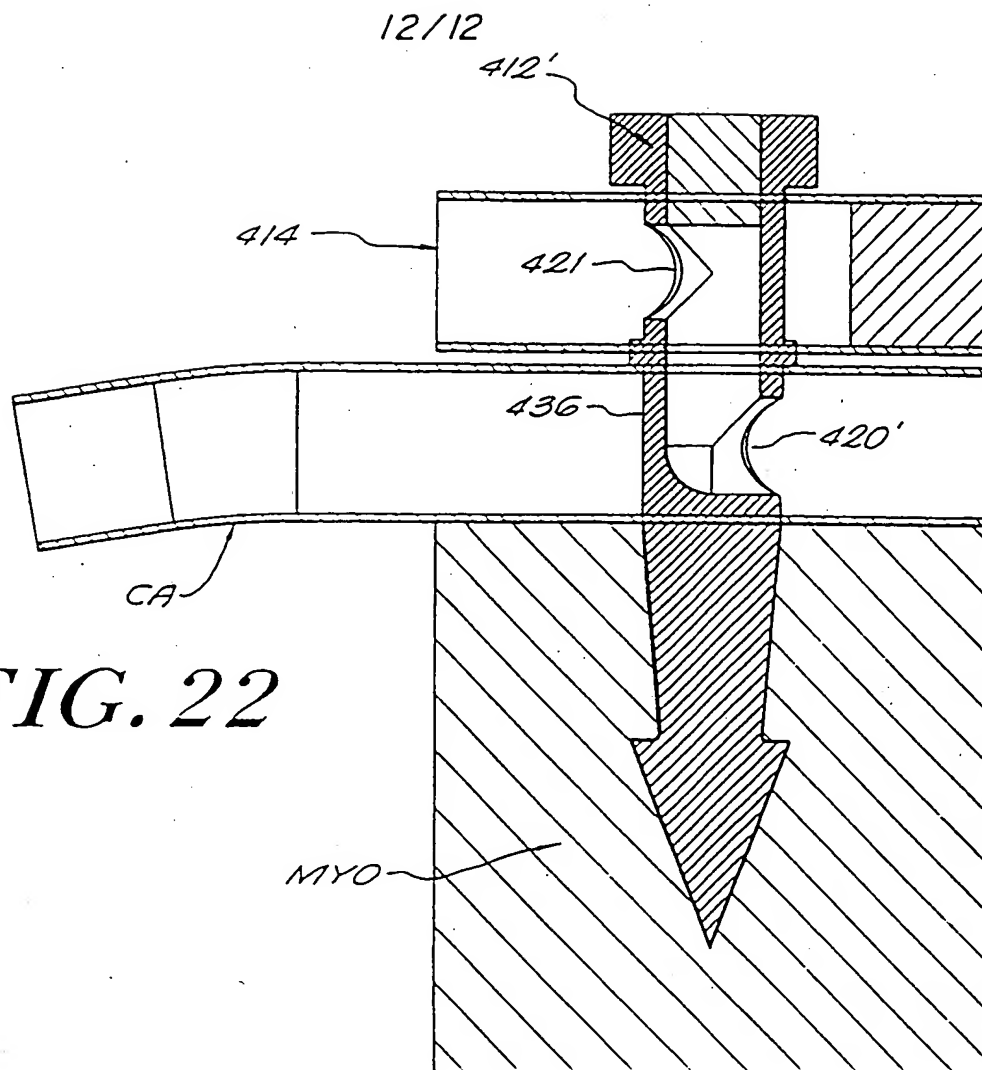


**FIG. 20**

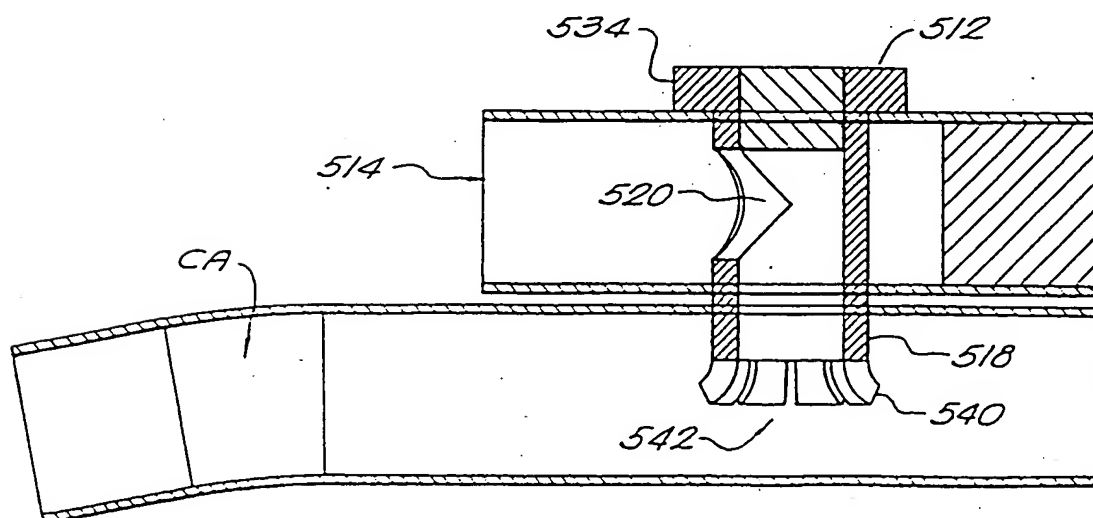


**FIG. 21**

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**FIG. 22**



**FIG. 23**

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